

Application No. 10/804,604
Response Dated December 4, 2006
Reply to Office Action of June 5, 2006

REMARKS

I. Summary of Office Action

The drawings were objected to under 37 C.F.R. § 1.83(a) for failing to show every feature of the invention specified in the claims, specifically the rods of claim 9.

The disclosure was objected to due to an informality on page 23 of the specification where the specification refers to Figure 5, when there are only four figures.

Claim 16 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to provide a sufficient antecedent basis for "the magnetic particles" limitation in line 1.

Claims 1-43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of U.S. Patent No. 5,336,263 to Ersek et al. (hereinafter "Ersek") and A.D. Gruneberger, "Development of and Initial Clinical Experiences with a Magnetic Urethral Closure Device", Urologe A, 26:106-111 (1987) (hereinafter "Gruneberger").

II. Summary of Applicant's Reply to Office Action

Applicant has amended the specification on page 23 to refer to FIG. 4 instead of FIG. 5. No new matter has been added.

Applicant has amended claim 16 to depend on claim 15 instead of claim 14.

Applicant has added claims 44-47.

The Examiner's objections to the drawings for failing to show the rods of claim 9 are respectfully traversed.

The Examiner's rejections of claims 1-43 are respectfully traversed.

III. 37 C.F.R. § 1.83(a) Objection

Applicant respectfully traverses the Examiner's objection to the drawings for failing to show the rods of claim 9 under 37 C.F.R. § 1.83(a). FIG. 1 illustrates an exemplary augmenting composition containing magnetic particles (specification at 20). FIG. 1 is only a representative example of the many embodiments of the invention. This representative example includes the rods of claim 9 since the specification defines "'particles'" as including material configurations ... such as rods" (specification at 10-11).

IV. 35 U.S.C. § 103 Rejection

The Examiner rejected claims 1-43 under 35 U.S.C. § 103(a) as being unpatentable over Ersek in view of Gruneberger. Applicant respectfully traverses the Examiner's rejection.

Claim 1, which is independent, is directed to a method of augmenting soft tissue in a body and requires selecting an augmenting agent and depositing the augmenting agent in soft tissue. Claims 2-13 depend from claim 1.

Claim 14, which is also independent, is directed to a method of forming a sphincter surrounding a portion of a body lumen and comprises a step of injecting an active augmenting agent into tissue surrounding the lumen. Claims 15-28 depend from claim 14.

Claim 29, which also is independent, is directed to a method of urging a patient's body tissue passageway toward closure and requires implanting mutually attracting magnetic bodies at locations that are circumferential of the passageway. Claims 30-41 depend from claim 29.

Claims 42 and 43 are independent and are directed to methods of urging a patient's body tissue passageway toward closure. Claim 42 requires implanting permanent magnetic bodies in the patient's body at locations that are spaced from one another circumferentially about the passageway. Claim 43 requires at least two magnetic bodies.

The Examiner alleged that "Gruneberger shows...two magnetic rods [that] pull on each other to narrow a urethra. It would have been obvious to one of ordinary skill in the art, at the time of the invention, to make the [Ersek] particles magnetic in order to increase the effectiveness of the treatment of the Ersek et al. invention, as magnetized urological incontinence treatments are well known in the art, and as taught by Gruneberger" (Office Action at 4).

Claims 1-28

Applicant notes that Ersek teaches that tissue augmentation preferably simulates the resilience of the injection site (Ersek, col. 5 ll 61-63) and can therefore gradually open and close in response to varying levels of fluid pressure inside the urethra. Gruneberger teaches a urethral closure device that operates in only one of two discrete states:

Application No. 10/804,604
Response Dated December 4, 2006
Reply to Office Action of June 5, 2006

open or closed. Applicant asserts that the Examiner's characterization of Gruneberger as showing "two magnetic rods [that] pull on each other to narrow a urethra" is inaccurate, because the Gruneberger device does not "narrow," but completely closes. The open state requires that, of the two Gruneberger magnets, one (identified below as the "closing" magnet) must be completely removed from the patient's body whenever it is desired to void the bladder.

Gruneberger sets forth difficulties and dangers associated with the use of magnets. Gruneberger discusses that pressure necrosis can result from the attractive forces of the magnet. Gruneberger also requires that there must be histocompatibility - between the magnet and the surrounding tissue - to prevent infection or other problems.

Therefore, even if the Examiner's allegation that "magnetized urological incontinence treatments are well known in the art" (Office Action at 4) is true, Gruneberger's use of magnets is not generally extensible to other incontinence treatments. Because of the risks that Gruneberger identified, Gruneberger requires that the closing magnet be removable. This way a doctor can fit a patient with different closing magnets,

Application No. 10/804,604
Response Dated December 4, 2006
Reply to Office Action of June 5, 2006

should an initial prescription be incorrect. The closing magnet must also be situated in such a way that the surrounding tissue is accessible and easily inspectable (Gruneberger at 10-11). By requiring a removable magnet, Gruneberger teaches two discrete states where the magnet is either inserted and fully engaged in the magnetic field for continence or it is not. The Gruneberger device cannot have resilience, because the removable magnet must be held firmly in place. Unlike Ersek's device, the Gruneberger device is an "on/off" system that cannot provide augmentation.

In view of the problems that Gruneberger associates with magnets, applicant asserts that (1) in neither Ersek nor Gruneberger is there a suggestion to modify Ersek as the Examiner proposed; and (2) such a modification would render Ersek unfit for its intended purpose (augmentation) because the removal and insertion of the closing magnet would interfere with the ability of the device to gradually open and close. (See M.P.E.P. § 2143.01, Part V.)

Claims 1-43

Applicant asserts that the Examiner improperly has relied on the level of skill in the art to provide a suggestion

Application No. 10/804,604
Response Dated December 4, 2006
Reply to Office Action of June 5, 2006

to combine Ersek and Gruneberger. See *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308 (Fed. Cir. 1999). Applicants assert that the Examiner, therefore, has not established *prima facie* obviousness.

Applicant also asserts that "the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." (M.P.E.P. § 2143.01, Part III). In this case, even if Gruneberger could be combined with Ersek to arrive at the claimed inventions, no such desirability of the combination exists because of the aforementioned problems that Gruneberger identified in connection with the use of magnets.

For at least the foregoing reasons, applicants assert that claims 1-43 are not obvious from Ersek in view of Gruneberger and respectfully request that the Examiner's rejections be withdrawn.

Application No. 10/804,604
Response Dated December 4, 2006
Reply to Office Action of June 5, 2006

V. Conclusion

In light of the foregoing amendments and remarks, the applicant respectfully submits that claims 1-43 are in condition for allowance. Applicant respectfully submits also that claims 44-47 are allowable. Reconsideration and allowance of this application are accordingly respectfully requested. Applicant notes that there may be other arguments in support of patentability of the claims and reserves the right to raise any such argument in the future.

Respectfully submitted,



William Z. Nakhleh
Registration No. 42,924
Attorney for Applicant
Fish & Neave IP Group
Ropes & Gray LLP
Customer No. 1473
700 12th Street, NW Suite 900
Washington, D.C. 20005
Tel.: (202) 508-4654
Fax : (202) 383-7764